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9 CFR Part 381

Irradiation of Poultry Products; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket 90-011P]

RIN: 0583-AB27

Irradiation of Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the poultry products inspection regulations to permit the use of ionizing radiation sources, as prescribed by the Food and Drug Administration's (FDA) regulations, to treat (1) fresh or frozen, uncooked whole poultry carcasses or parts known as "ready to cook poultry," which includes such poultry products as fresh or frozen, uncooked ground, hand-boned, and skinless poultry and (2) mechanically separated poultry product, which is a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses. Ionizing radiation would be applied for the purpose of controlling and reducing foodborne pathogens, such as *Salmonella, Campylobacter*, and *Listeria monocytogenes*, that may be present in raw poultry, in order to reduce the potential for foodborne illness.

DATES: Comments must be received on or before July 6, 1992.

ADDRESSES: Written comments to: Policy Office, Attn. Linda Carey, FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided under the Poultry Products Inspection Act to: Mr. Donald Derr, (202) 205-0675. (See also "Comments" under Supplementary Information.)

FOR FURTHER INFORMATION CONTACT: Mr. Donald Derr, Deputy Director for Scientific Support, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, Area Code (202) 205-0675.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined in accordance with Executive Order 12291 that this proposed rule is not a "major rule." It would not result in an annual effect on the economy of $100 million or more. There would be no major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It will not have a significant adverse effect on competition, employment, investment, productivity, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Polutry Products Inspection Act (PPIA) from imposing and marking, labeling, packaging, or ingredient requirements on federally inspected poultry products that are in addition to, or different than those imposed under the PPIA. States and local jurisdications may, however, exercise concurrent jurisdiction over poultry products that are outside official establishments for the purpose of preventing the distribution of poultry products that are misbranded or adulterated under the PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the PPIA, States that maintain poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the PPIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

This rule is not intended to have retroactive effect. There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule. However, the administrative procedures specified in 9 CFR 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an inspector relating to inspection services provided under the PPIA. The administrative procedures specified in 9 CFR part 381, subpart W, must be exhausted prior to any judicial challenge of the application of the provisions of this rule with respect to labeling decisions.

Effect on Small Entities

The Administrator has made an initial determination that this proposed rule will not have a significant economic impact upon a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). Facilities wishing to irradiate poultry would incur costs associated with implementing an adequate quality control system. Any other costs should be attributable to the normal costs of starting production of a new product.

Summary of Cost and Benefits

The potential benefits of irradiating poultry are reductions in health costs associated with foodborne illness. Irradiation can be expected to eliminate pathogenic bacteria such as *Salmonella, Campylobacter*, and *Listeria monocytogenes* that may be present in raw polutry. Therefore, benefits can be viewed as being proportional to the amount of poultry irradiated, i.e., if half of raw poultry were irradiated, the benefits would be equal to half of the current health costs attributable to improper handling/cooking of raw poultry. However, benefits could accrue at a higher rate if poultry irradiation were focused on product consumed by higher risk populations who are more susceptible to foodborne illness.

The Centers for Disease Control estimates that approximately 2 million *Salmonella* related illnesses in humans occur annually and that the number of *Campylobacter* related illnesses is larger. Epidemiological studies show that despite educational efforts, improper handling and cooking of contaminated poultry continues to be identified as a cause for specific cases of illness. Thus, irradiation of poultry to eliminate bacteria in raw product has the potential to reduce the incidence of foodborne illness. The exact level of reduction will not be known until epidemiological studies can be conducted including a category for individuals routinely consuming irradiated poultry and specific data on vulnerable populations.

Economic Research Service (ERS) research estimates potential benefit/cost ratios of 2.2 to 2.8 for irradiating chicken. In developing these ratios, the ERS research considered the medical and productivity costs associated with foodborne illness. The cost estimates did not include costs of chronic medical conditions that may result from acute foodborne illness. The costs also did not include losses such as pain and suffering. If such cost were included, the total benefits would be greater.

The ERS study estimated the cost of irradiating chicken at $.015 per pound for a medium or large chicken processing plant. Costs did not include transportation, promotion or disposal of low-level radioactive waste.

A subsequent ERS study has estimated that the cost of irradiating chicken would range from 0.86 to 1.3 cents per pound depending on the

overall volume of product.[1] These latter estimates were developed for an integrated, inplant facility and did not include transportation costs and other costs associated with moving product to an irradiation facility.

Based on available research and studies, FSIS has concluded that poultry irradiation will have a benefit/cost ratio greater than one, i.e., for every dollar expended on irradiation, there will be more than a dollar of medical and productivity costs avoided. In other words, FSIS believes that the irradiation of poultry provides positive net public health benefits. ERS currently estimates that, if ten percent of U.S. chicken production were irradiated, net public health benefits would range from 35 to 50 million dollars annually (based on 1991 estimates).

Besides public health and productivity benefits, there are other potential benefits for the irradiation of poultry. For example, there is a potential for increasing the exportation of poultry products. There are countries that are interested in importing irradiated poultry products from the United States.

Paperwork

Before an establishment may irradiate poultry, the operator would apply to and obtain approval from FSIS for a Grant of Inspection. Facilities whose only poultry processing activities consist of irradiation of pre-packaged raw poultry would be required to submit and obtain approval of a quality control system in lieu of more detailed drawings and specifications required by applicants for inspection who handle exposed poultry products. Facilities which conduct both irradiation processing and other poultry processing would also submit, in addition to information required under 9 CFR 381.19, a description of their quality control system. FSIS would receive, evaluate, and either approve or disapprove requests for such quality control systems. The quality control system would be placed on file in the establishment and be available to any duly authorized representative of the Secretary. The information collection requirements contained in this rule have been submitted to the Office of Management and Budget for approval.

Comments

Interested persons are invited to submit written comments concerning this proposal. Written comments should be sent to the Policy Office at the above address and should refer to Docket Number 90-011P. Any person desiring an opportunity for an oral presentation of views as provided under the Poultry Products Inspection Act, should make such request to Mr. Donald Deer at (202) 205-0675 so that arrangements can be made for such views to be presented. All comments submitted in response to the proposal will be available for public inspection in the Policy Office, between 9:00 a.m. to 12:30 p.m. and 1:30 p.m. to 4 p.m., Monday through Friday.

Background

Need for Irradiation of Poultry

Over the last few years, the public has become more aware of the threat of foodborne illnesses caused by pathogens, disease-causing microorganisms. Pathogens of concern include *Listeria monocytogenes, Campylobacter jejuni,* and *Salmonella.* These bacteria cannot be detected by sight, smell or taste.

Listeria monocytogenes is widely distributed in the environment, has the ability to survive for long periods of time under adverse conditions, and is capable of growing at refrigerator temperatures. During the late 1980's, *Listeria monocytogenes* was documented as a cause of human listeriosis, which is foodborne illness. The extent of the illnesses ranged from very mild to fata. For pregnant women, newborns and infants, and adults with a compromised immune system, *Listeria monocytogenes* can be life-threatening. As a result, this bacterium has become recognized as an important foodborne pathogen.

Campylobacter jejuni naturally lives as a harmless inhabitant in the intestinal tract of many warm blooded animals including poultry. *Campylobacter* has been widely reported throughout the world as a cause of human gastroenteritis known as campylobacteriosis. In many countries, the rate of isolation of *Campylobacter jejuni* from patients with diarrhea is higher than the isolation rate for *Salmonella.* Epidemiologists believe that consumption of undercooked or uncooked poultry may cause some sporadic cases of campylobacteriosis.

Salmonellae are intestinal bacteria frequently found in warm-blooded food animals such as livestock and poultry. Many animals which are not clinically ill are nevertheless carriers of these organisms. With current slaughter and processing practices, the bacteria carried by the live animals may be present in raw meat and poultry products.

In a 1982 to 1984 statistically based FSIS national survey of young chickens, *Salmonella* was recovered from 35.2 percent of the broiler carcasses.[2] Recent European research has shown that incidences of *Salmonella* contamination cannot be reduced much below 10 percent of the broiler carcasses with even the most stringent prevention practices.[3]

As discussed previously, *Salmonella, Campylobacter,* and *Listeria monocytogenes* are present in raw poultry and their presence leads to public health costs, reductions in worker productivity, and other intangible costs. Children, the elderly, and immuno-compromised individuals are particularly vulnerable. Therefore, in an attempt to lower levels of contamination from *Listeria monocytogenes, Campylobacter, Salmonella,* and other disease-causing microorganisms, FSIS is proposing to amend the poultry products inspection regulations to permit the use of ionizing radiation sources, as prescribed by FDA regulation (21 CFR 179.26), to treat (1) fresh or frozen, uncooked whole poultry carcasses or parts known as "ready to cook poultry" with in the meaning of 9 CFR 381.1(b)(44), which includes such poultry products as fresh or frozen, uncooked ground, hand-boned, and skinless poultry and (2) mechanically separated poultry product, which is a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses and ground poultry.

Food Additive Uses for Irradiation

A source of ionizing radiation (gamma radiation, electron radiation, and X-radiation) is expressly defined as a good additive in section 201(s) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 321(s)), and, therefore, would be regulated as a food additive by the FDA. Prior to May 2, 1990, FDA regulations (21 CFR part 179) permitted irradiation only for the following purposes: (a) control of *Trichinella spiralis* in pork carcasses or fresh, non-heat-processed cuts of pork carcasses,

[1] This figure is based on a study titled "An Economic Analysis of Electron Accelerators and Cobalt-60 for Irradiating Food," Economic Research Service, USDA, 1989. A copy of this study is available, for a fee, from ERS-NASS, P.O. Box 1608, Rockville, MD 20850 or by calling 1-800-999-6779.

[2] "*Salmonella* in Broiler and Overflow Chill Tank Water 1982-1984." A copy of this document is available from the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[3] "Adequate Protection of the Public Against Food-Transmitted Diseases of Microbial Aetiology." 1989. D.A.A. Mossel. International Journal of Food Microbiology. Volume 9, pages 271-294. A copy of this document is available from the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(b) growth and maturation inhibition of fresh foods, (c) disinfestation of arthropod pest in food, (d) microbial disinfestation of dry or dehydrated enzyme preparations, and (3) microbial disinfestation of dry or dehydrated aromatic vegetable substances and blends of these substances.

Irradiated Poultry

On October 24, 1986, FSIS petitioned FDA to permit irradiation pasteurization of retail packaged, frozen or fresh, uncooked (1) whole carcasses or disjointed portions of such carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b) (44), or (2) poultry products in which the poultry product portion consists solely of mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses and parts of carcasses). On February 20, 1987, FDA announced in the **Federal Register** (52 FR 5343) that it had received a petition from FSIS proposing that 21 CFR 179.26 be amended to provide for the use of sources of ionizing radiation to control foodborne pathogens by reducing the level of microorganisms, such as *Salmonella* and *Campylobacter*, in poultry products. On March 3, 1987, FDA annouced in the **Federal Register** (52 FR 6391) that it had received a petition from Radiation Technology, Inc., (RTI), proposing that the food additive regulations be amended to provide for the safe use of a source of gamma radiation to irradiate poultry for the purpose of extending the shelf-life and reducing the risk of foodborne illness due to *Salmonella* contamination. On May 2, 1990, in response to petitions from RTI and FSIS, FDA amended its food additive regulations to permit the use of ionizing radiation sources for treatment of fresh or frozen, uncooked poultry and mechanically separated poultry product to control foodborne pathogens (55 FR 18538).

During its technical review of the merits of the petitioner's requests, FDA evaluated (1) toxicity studies on irradiated chicken, (2) reports on the efficacy of the process and on the microbiological safety of the product, and (3) studies of the nutritional adequacy of the irradiated product. After a thorough review of available information and data, FDA concluded that irradiation of poultry up to an absorbed dose of 3 kiloGray (kGy)[4] does not present a toxicological hazard and controls the levels of microorganisms in poultry, particularly of such foodborne pathogens as *Salmonella* and *Campylobacter*, and that consumption of irradiated poultry will not have an adverse impact on the nutritional value of a person's diet. A brief discussion of the studies reviewed and FDA's conclusions is presented below.

FDA Evaluation of Toxicity Studies

FDA reviewed several animal feeding studies which were submitted as part of the RTI petition to determine the safety of irradiated poultry when fed to mice, rats and beagles. The studies consisted of an 80-week carcinogenicity study in mice; a multigeneration study in rats; a 2-year chronic rate study; and a 1-year beagle study. Because of deficiencies in the data submitted with the 80-week carcinogencity study, FDA determined that the study could not be relied upon as a primary basis for evaluating the safety of irradiated poultry. FDA then reviewed the remaining studies listed above. Upon evaluation, FDA scientists concluded "* * * the studies appeared to be of high quality and that there was no evidence of adverse effects attributable to consumption of diets containing chicken irradiated at 3 or 6 kGy." (55 FR 18539)

In an effort to provide further assurance as to the safety of irradiated poultry, FDA also evaluated other available studies on the subject contained in its files. These studies, conducted by Raltech Scientific Services, included a chronic feeding study in mice; a chronic feeding study in dogs; teratology studies in four species; a dominant lethal test in mice; a sex-linked recessive test in *Drosophila melanogaster;* and an Ames mutagenicity test. Upon evaluation, FDA concluded that it "* * * found no evidence in any of the Raltech studies of adverse effects that could be attributed to irradiation of chicken at doses of up to 59 kGy." (55 FR 18540)

FDA scientists also evaluated several genetic toxicity studies conducted by the Federal Research Centre for Nutrition. The studies included a reverse mutation test in *Salmonella typhimurium;* a sister chromatid exchange and hypoxanthine-guanine phosphoribosyl transferase mutation assay in hamster ovary cells; and a micronucleus test and a bone marrow sister chromatid exchange in spermatogonia, all in rodents. FDA scientists did note methodological deficiencies in the other studies which limited their usefulness, but "* * * found no evidence in any of these studies that indicated that irradiated chicken was mutagenic." (55 FR 18541)

FDA carefully reviewed all of the submitted studies from the petitioners and other studies on file on the toxicological effects of irradiated chicken and concluded that "* * * based on all the evidence before it, that the irradiation of poultry at the petitioned level of up to 3 kGy does not present a toxicological hazard." (55 FR 18541)

Microbiological Effectiveness

FDA reviewed several reports and published papers describing the effectiveness of low-dose irradiation in reducing the number of microorganisms on poultry and other foods. A number of the reports reviewed by FDA pointed out that the radiation dose necessary to reduce the initial population of *Salmonella* by 90 percent, the D-value or decimal reduction dose in kGy, ranges from less than 0.5 kGy to approximately 1 kGy depending upon such factors as the microbial strain and/or the temperature at which irradiation is performed. A 2 decimal reduction would result in 99 percent destruction and a 3 decimal reduction would be 99.9 percent. The absorbed dose range (from the minimum does to the maximum dose) of this proposed rule would control *Salmonella* to the 3 decimal reduction level, a 99.9 percent reduction of *Salmonella.*[5]

Other microorganisms of public health significance, specifically *Campylobacter*, are even more radiation-sensitive than *Salmonella.* After review of the referenced publications as well as other published data, FDA found that "* * * irradiation at doses of up to 3 kGy is effective in lowering the burden of microorganisms in poultry." (55 FR 18542) While irradiation at 3 kGy reduces the number of many pathogen and spoilage bacteria, it does not sterilize food nor eliminate *Clostridium botulinum*, a relatively radiation-resistant spore-forming microorganism. FDA reviewed several studies on *C. botulinum* growth and toxin production on poultry skins. At 3 kGy enough non-spore-forming bacteria survive so that normal signs of spoilage would become evident before *C. botulinum*, if present, could render the

[4] 1 kiloGray (kGy) = 100 kilorad (krad).

[5] Heath, J.L., Owens, S.L., and Tesch, S., "Effects of High-Energy Electron Irradiation of Chicken Meat on *Salmonella* and Aerobic Plate Count," 1990 Poultry Science, Vol. 69., Pgs. 150–156, 1990. Thayer, Donald W., Boyd, G., Muller, W.S., Lipson, C.A., Hayne, W.C., and Baer, S.H., "Radiation Resistance of *Salmonella*," Journal of Industrial Microbiology, Vol. 5. Pgs. 383–390, 1990. Copies of these documents are available from the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

product toxic. FDA concluded that "* * * irradiation of poultry at 3 kGy does not result in any additional health hazard from *C. botulinum.*" (55 FR 18541)

Recent publications suggest that gamma radiation would be effective in reducing *Listeria monocytogenes* on chicken at low doses. The sensitivity of *Listeria monocytogenes* to ionizing radiation is similar to *Salmonella.* Therefore, irradiation of chicken carcasses at doses sufficient to reduce *Salmonella* levels would also be effective in reducing *Listeria monocytogenes* levels.[6]

FDA Evaluation of Nutritional Considerations

In addition to determining the safety of irradiating poultry and the efficacy of the process, FDA reviewed data to determine whether irradiation of poultry would have an adverse effect on the nutritional value of food. After reviewing the studies and reports, FDA concluded that the data show that "irradiation at the doses used does not have a deleterious effect on the levels or the bioavailability of the nutrients in chicken." (55 FR 18542) FDA then concluded that "* * * irradiation of poultry at doses of up to 3 kGy will not have an adverse impact on the nutritional value of a person's diet." (55 FR 18542)

Application and Dose Range of Irradiation

Ionizing radiation would be applied for the purpose of controlling and reducing foodborne pathogens such as *Salmonella, Campylobacter,* and *Listeria monocytogenes* that may be present on the poultry product in order to reduce the potential for foodborne illness. FSIS is proposing an absorbed dose range with a minimum absorbed dose of 1.5 kGy and a maximum absorbed dose of 3.0 kGy. Such a range provides for the smallest practical range that can be administered, and the most effective treatment. The minimum absorbed dose is proposed as a means of assuring an effective reduction of the foodborne pathogens listed above. FDA did not identify a minimum absorbed dose in its final rule published on May 2, 1990, in the **Federal Register** (55 FR pages 18538 through 18544), stating "(t)he minimum dose needed to control pathogenic organisms on poultry can vary with the particular microorganism * * *." (55 FR 18541) Further, FDA said FSIS had the regulatory authority to establish a specific minimum dose.

Products Affected by the Proposed Rule

FDA, in its May 2, 1990, regulation, limited the use of ionizing radiation for the treatment of poultry to (1) whole carcasses or disjointed carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b)(44), or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses).

After the Agency petitioned FDA for the irradiation of (1) whole carcasses or disjointed carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.1(b)(44), or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses), there was concern that these product category descriptions might not include such poultry products as fresh or frozen uncooked ground, boneless, and skinless poultry. FSIS sent FDA a letter seeking clarification of this matter. A November 8, 1991, letter from FDA stated that "[w]e would certainly consider fresh or frozen, uncooked hand-boned, skinless, and ground poultry to be among the products that may be irradiated under 21 CFR 179.26."

Therefore, on the basis of FDA's approval of our petition and FDA's November 8, 1991, letter, FSIS proposes that poultry to be irradiated must be (1) fresh or frozen, uncooked whole poultry carcasses or parts known as "ready to cook poultry," which includes such poultry products as fresh or frozen, uncooked ground, hand-boned, and skinless poultry and (2) mechanically separated poultry product, which is a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses. Poultry products permitted to be irradiated would include any uncooked poultry to which no other ingredients have been added.

The Agency believes it is inappropriate to provide for irradiation of cooked poultry products because, having been cooked, they should be free of the foodborne pathogens intended to be eliminated by irradiation. Also, the Agency did not petition for the irradiation of cured poultry nor poultry products with other ingredients added because no adequate study existed regarding the irradiation of such poultry products. Therefore, this proposed rule does not permit the irradiation of cooked poultry products, cured poultry products, or poultry products with the addition of other ingredients.

Packaging Requirements

FDA stated in its May 2, 1990, regulation that "FSIS * * * can establish specific packaging requirements * * * consistent with current good manufacturing practice * * *." (55 FR 18542) Therefore, FDA concluded that FSIS could establish any packaging requirement as long as those requirements comply with 21 CFR 179.25 and 179.26.

To best ensure a reduction of the microbial load on poultry product, FSIS believes that all irradiated poultry would be packaged, in compliance with 21 CFR 179.25 and 179.26, prior to irradiation and remain in the same package through the distribution in commerce to the point of purchase. Once a package of irradiated poultry product is opened, the product is subject to the same possible contaminants as any unpackaged poultry; therefore, the special benefits inherent to irradiated poultry would possibly be nullified. Therefore, to provide poultry products with the highest potential for reduced microbial contaminates, FSIS proposes that poultry products to be irradiated be packaged, then irradiated, and remain in that package until the point of purchase.

FSIS proposes to require, as part of a quality control system, that a guaranty or statement of assurance accompany each shipment of poultry product. The guaranty or statement of assurance would identify that the packaging material is approved, in accordance with 21 CFR 179.45, as a packaging material for use during the irradiation of pre-packaged foods. Product not accompnied by such a guaranty or statement of assurance would not be permitted to be irradiated. FDA defines in 21 CFR 179.45 the packaging material which may be used during the irradiation of pre-packaged foods.

In addition, FDA noted that use of air-permeable packaging materials provides an extra margin of safety from *C. botulinum* toxin production and spoilage in chicken incubated both aerobically (with oxygen) and anaerobically (without oxygen). FDA stated that "[b]ecause the petitioner [USDA] requested that only air-permeable packaging be permitted, FDA is including a provision in the regulation that packaging used shall not exclude

[6] Huhtanen, C.N., Jenkins, R.K., and Thayer, D.W., "Gamma Radiation Sensitivity of *Listeria monocytogenes*," *Journal of Food Protection,* Vol. 52, No. 9, pages 610–613, September 1989 and Patterson, M., "Sensitivity of *Listeria monocytogenes* to Irradiation on Poultry Meat and in Phosphate-Buffered Saline," Letters in Applied Microbiology, Vol. 8, No. 5, pages 181–184, February 1989. Copies of these documents are available from the Office of the FSIS Hearing Clerk, Room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

oxygen." (55 FR 18542) Therefore, as an extra margin of safety, FSIS proposes to require that the guaranty or statement of assurance also certify that the packaging material does not exclude oxygen, but does exclude moisture and microorganisms from penetrating the package barrier.

Labeling Requirements

On April 18, 1986, FDA published a final rule in the **Federal Register** (50 FR 13376) amending 21 CFR 179: "Irradiation in the Production, Processing and Handling of Food." That rule addressed the labeling of irradiated foods, including conditions of safe use, as well as misbranding considerations. The FDA labeling requirements apply to all uses of ionizing radiation for the treatment of food. In summary, the relevant parts are as follows:

—The label and labeling of packages of irradiated foods must bear the international radiation logo displayed below:

—To better inform the public that products have been treated by irradiation, the packages must also bear the statement, "Treated with Radiation" or "Treated by Irradiation."

In 50 FR 13376, there was a provision (21 CFR 179.26(c)(4)) that the statements "Treated with Radiation" or "Treated by Irradiation" need only be used for a 2-year period, if it was believed that the public had become familiar with the fact that products were irradiated. However, on April 18, 1988, FDA published a rule (53 FR 12756) which extended the 21 CFR 179.26(c)(4) provision, thus requiring the labeling statements for another 2-year period. Again, on April 18, 1990, FDA amended its regulation on the labeling of irradiated food (55 FR 14413) and at that time removed the 21 CFR 179.26(c)(4) provision. Therefore, FDA is permanently requiring that the statement "Treated with Radiation" or "Treated by Irradiation" accompany the logo. The reason for the change was that there was no basis for determining when the statement and the logo would no longer be necessary as a means to inform consumers that a food had been irradiated.

FDA regulations apply the retail labeling requirement only to food which has itself been irradiated. The preamble to the FDA final rule also endorses the use of optional labeling statements which describe the type or purpose of irradiation treatment applied, and the use of optional, educational statements about irradiation.

FSIS has determined that the labeling requirements of the FDA final rule provide information to the consumer which is accurate and not misleading. FSIS is obligated to consider whether differences exist between meat and poultry products and the food products that FDA regulates, in case different or additional labeling requirements may be warranted for irradiated meat and poultry products. The Agency believes that FDA labeling requirements are adequate to inform the public that products have been treated with radiation and that no difference exists, and that a regulation for different or additional statements is not necessary.

Irradiation Statements and Logo—To assure that labeling statements pertaining to irradiation would be clearly indicated on product labeling, FSIS proposes that the required statements on irradiated products would appear as a qualifier contiguous to the product name and in letters of the same style, color and type as the product name. Letters used for the qualifying statement would be no less than one-third the size of the largest letter in the product name.

FSIS believes that it would not be appropriate to propose a different logo for irradiated poultry products than that accepted by FDA. FSIS has determined that the irradiation logo would be colored green to be consistent with the international logo. The green logo is recommended by the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Atomic Energy Association, and the International Trade Center (ITC) for its symbolic intent, green being representative of agricultural commodities.

Labeling Requirements—The following information would be required on irradiated poultry product labels:

(a) The logo and a statement that the product has been irradiated, as required by FDA in 21 CFR 179.26(c), and

(b) The handling statement, "Keep Refrigerated" or "Keep Frozen," as appropriate. Such statements are currently required, in accordance with 9 CFR 381.125, to be on the labeling of all products that are not shelf stable (e.g., products not canned or dried).

Optional Labeling Statement About Irradiation—Educational statements about irradiation (e.g., how the product was treated, product safety, process benefits) may be applied to labeling provided the information is not false or misleading. Such statements would be evaluated by the Agency on a case-by-case basis. Any rules of general applicability formulated through this case-by-case review will be addressed in future rulemaking. Such statements should pertain to the general technology of food irradiation, or the application used for the food so labeled, such as "Irradiated to Control Foodborne Bacteria." Various truthful phrases could be used so long as the explanatory language is applicable and not misleading. Statements implying that irradiation imparts special properties to a particular brand of product, as opposed to a food category, would not be permitted on labeling.

Labeling statements about the purpose of irradiation for a specific food item would be permitted when the statement reflects the approved irradiation application for that food. For example, poultry irradiated according to this proposed rule could be labeled with a statement referring to control of foodborne bacteria, but could not be labeled with a statement that the product has an extended shelf life or is "pathogen free," since the validity of such claims have not been evaluated by the Agency.

Application for Inspection

Before an establishment may irradiate poultry, the operator would have to apply to and obtain approval from FSIS for a Grant of Inspection as described in the poultry products inspection regulations (9 CFR 381.16) because the facilities are considered processing establishments, and the Agency must recognize them as such. However, facilities whose only processing of poultry consists of irradiation of pre-packaged raw poultry would not need to meet the blueprint and specification requirements of 9 CFR 381.19, since only pre-packaged products would be processed.

Facilities whose only processing of poultry consists of irradiation of pre-packaged raw poultry would submit a description of their quality control system along with their application for inspection. The quality control system would be evaluated and approved in accordance with section 381.145(e) of the poultry products inspection regulations. Inspection for radiation processing would be granted based upon the approval of the quality control system. Establishments which conduct operations requiring inspection in addition to irradiation of pre-packaged raw poultry would provide with their

applications for inspection a description of their proposed quality control system in addition to the information required under 9 CFR 381.19 (a) through (f).

Facilities whose only processing of poultry consists of irradiation of pre-packaged raw poultry would only be subject to certain sanitation, facility, and operating requirements as described in the poultry products inspection regulations (9 CFR 381.46 to 381.61); since only pre-packaged product would be processed. These existing regulations for sanitation, facility, and operating requirements generally are measures to prevent exposed-product cross-contamination, which is not applicable in irradiation facilities.

As part of their quality control system, the irradiation facility would need to incorporate the necessary sanitation, facility, and operating requirements, as determined by the Administrator, to ensure that the irradiation facility is kept clean, sanitary, and in good repair.

Irradiation facilities using radionuclide sources would be licensed by the Nuclear Regulatory Commission (NRC) (10 CFR parts 2, 19, 20, 30, 71, 150 and 170), or by the appropriate State government acting under authority granted by the NRC. The NRC or the State government would also conduct compliance and safety inspections in the plant. Occupational Safety and Health Administration (OSHA) or the appropriate State government acting under authority granted by OSHA regulates all radiation sources not regulated by the NRC. This would include sources of electron beam radiation and x-radiation. Irradiation facilities possessing or using these sources would have registered such sources with the State. Facilities using these sources are subject to inspection by OSHA or by the State in an OSHA State Plan State. FDA (HHS Publication 83–8203),[7] OSHA (29 CFR part 1910), and the National Institute of Standards and Technology (NIST) (NBS Handbook 142) [8] are also involved in regulating the operational aspects of irradiation facilities.

Each of these agencies has imposed requirements applicable to irradiation operations that reflect the scope of their particular authorities, including ones which are vital to plant safety and public health. All applicants for Federal poultry products inspection service would be expected to submit documentation as part of a quality control system showing that they have licensing and/or possess radiation sources registered by the NRC or appropriate State agency acting under authority granted by the NRC and with OSHA or the appropriate State agency acting under authority granted by OSHA.

Compliance with Licensing/ Registration/Safety

Irradiation facilities operating under FSIS inspection would be responsible for proper controls to prevent FSIS employees from being exposed to radiation in excess of acceptable limits established by OSHA and NRC. In accordance with OSHA's regulation (29 CFR 1910.96), each radiation area must be "conspicuously posted" with appropriate signs and/or barriers. Work practices not in accordance with 29 CFR 1910.96 would result in the withdrawal of FSIS employees from the irradiation facility. Additionally, such work practices would lead to initiation of the termination process of quality control systems in accordance with the established procedures in 9 CFR 381.145(g).

In accordance with FSIS Directive 4791.1, FSIS would ensure safe and healthful working conditions for FSIS employees assigned to irradiation facilities. This would be accomplished by engineering controls, administrative controls, work practice controls, or withdrawal of FSIS employees from the irradiation facility to the extent necessary to assure that employees are protected as provided under 29 CFR 1910.96. FSIS would maintain records of the radiation exposure of FSIS employees for whom personnel monitoring is required.

FSIS would provide appropriate specialized safety and radiological health training for FSIS employees assigned to irradiation facilities.

General Control

FSIS expects that poultry processing establishments may choose to add irradiation capabilities within their current facilities or contract with irradiation processors. Further, irradiation processors may purchase products for irradiation or provide irradiation processing on a contractual basis for product owners. In each case, all parties will be expected to maintain controls, to the extent of their responsibilities, under this regulation.

The Agency proposes that a quality control system in accordance with a new proposed 9 CFR 381.149 be required for irradiation processing. Most radiation processors presently irradiate commodities other than poultry, including medical supplies, polymers, and spices, and do not have adequate provisions for drainage, potable water, or refrigeration as required of other official USDA poultry establishments, except cold-storage warehouses. Therefore, the Agency would require that all poultry products first be prepared and packaged at official establishments that maintain such controls.

Quality Control System

FSIS proposes that, at a minimum, the operator of the irradiation facility must establish and comply with a quality control system which provides for the following:

1. Facility and Licensing Requirements: Procedures to ensure that the irradiation facility complies with the applicable provisions of Subpart H of the poultry products inspection regulations, as determined by the Administrator. In addition, if there were no permanent refrigerated storage capacity in the facility, there would need to be procedures to ensure that adequate refrigeration units would be made available during the irradiation of poultry.

As discussed earlier, irradiation processors would provide documentation showing that facilities using radionuclide sources are licensed by the NRC (10 CFR parts 2, 19, 20, 30, 71, 150 and 170), or by the appropriate State government acting under authority granted by the NRC. Documentation would also be provided showing that the facilities are registered with OSHA or the appropriate State government acting under authority granted by OSHA.

2. Training: Prior to irradiating poultry intended for commercial distribution, irradiation facilities would have to provide a statement in the quality control system certifying that their perssonel would operate under supervision of a person who has successfuly completed a course of instruction for operators of food irradiation facilities. Additionally, the statement would assure that the personnel have been trained in quality control, food technology, irradiation processing, and radiation health and safety.

Typically, FSIS would expect plant supervisors to have completed modules of instruction that include the fundamentals of food irradiation, e.g., facilities and equipment design and approval, processing procedures,

[7] A copy of this document is available from the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[8] A copy of this document is available from the Office of the FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

labeling, packaging, quality control system, and employee safety issues. The instruction would be of sufficient length of time to cover the subject matter, and use expert instructors in food irradiation. An example of a curriculum presently available to irradiation facility supervisors/managers is the Food Irradiation Process Control School (FIPCOS), sponsored by the Food and Agriculture Organization (FAO) of the United Nations and the International Atomic Energy Agency (IAEA). Although attendess of this school do not presently receive a formal certification of successful completion of the curriculum, their curriculum serves as a basis for presenting good manufacturing practices to irradiation supervisors/managers.

3. Poultry Product and Packaging Material: In order to ensure that a product receives an absorbed dose within the required range, criteria related to poultry product and packaging material would be identified in the quality control system and controlled. These criteria relate: The type of product to be irradiated (including the size, thickness, weight, and cut of product); the bulk density (the mass (weight) of a product unit divided by its total volume); the packaging material in direct contact with the product; the proper packing configuration of the product within the packaging material; and the proper packing configuration of the packaged product (size, shape, number, and weight of the packaged product units on a pallet or container to be transported through the radiation chamber).

For the packaging material, a guaranty or statement of assurance, as discussed earlier, would have to accompany each shipment of product. The guaranty or statement of assurance would state that the material complies with appropriate provisions of the FFDCA (21 U.S.C. 301 *et seq.)* allowing its use. In addition, the statement would provide assurance that the packaging material is air-permeable, but does exclude moisture and microorganisms from penetrating the package barrier.

4. Dosimetry: The quality control system would address the procedures and equipment for measuring the absorbed dose of ionizing radiation in the product. The accuracy of the dosimetry system would have to be demonstrated on experimental or previously irradiated product using the same dosimetry system and proposed quality control system procedures. For guidance, the existing standards and others proposed by the international organization, the American Society of Testing and Materials (ASTM), can be followed in documenting the accuracy of the dosimetry system.

ASTM Subcommittee E10.101, "Dosimetry for Radiation Processing," is composed of 165 international experts. The subcommittee is involved in the development of standard practices for the selection and application of dosimetry systems for radiation processing and for characterizing and qualifying food irradiation facilities. Eight standards have been published in Volume 12.02 of the Annual Book of ASTM Standards. Specifically, establishments irradiating poultry can obtain useful guidance from standards E1204—Practice for the Application of Dosimetry in the Characterization of a Gamma Irradiation Facility for Food Processing, E1261—Guide for the Selection and Application of Dosimetry Systems for Radiation Processing of Food, and E1431—Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing.[9] Other ASTM standards are being developed which will impact the use of dosimetry systems and at the time of publication will provide further guidance for radiation processing establishments.

To ensure accuracy, irradiation facilities would be expected to demonstrate that their dosimetry system is traceable and calibrated at least every 6 months, as recommended by ASTM, to the national standards specified by the National Institute of Standards and Technology (NIST). On a user-fee basis, NIST administers such a service. Each production lot must have at least one dosimeter positioned at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit.

The product would not be allowed to be reirradiated (i.e., the total absorbed dose cannot be administered more than once) since the absorbed dose of ionizing radiation is cumulative in the product. The total absorbed dose could be administered in more than one treatment (i.e., the absorbed dose from each partial treatment would be cumulated to result in the total absorbed dose) if documentation of the absorbed dose is assured throughout the product during each partial treatment and the process is continuous (occurring within the same day).

[9] These standards are found in Volume 12.02, Annual Book of ASTM Standards. A copy of these standards is available, for a fee, from the American Society of Testing and Materials (ASTM), 1916 Race St., Philadelphia, PA 19103–1187.

5. Labeling: The quality control system would address controls to assure that the labeling of the poultry product received from other sources is correct, as discussed earlier.

6. Handling, Storage, and Transportation: The quality control system would address procedures for the proper handling of poultry products. Such procedures would address conditions such as poultry with damaged packaging or improperly irradiated product. The quality control system would also address procedures for preventing cross-contamination, reirradiation, and commingling of irradiated and unirradiated products.

The quality control system would address maintenance of perishable poultry product at appropriate temperatures in accordance with 9 CFR 381.66, throughout radiation processing and shipment. Perishability of the poultry product is vastly affected by the temperature at which the product is held througout processing, as well as the amount of time the product is held at any given temperature. Since numbers of bacteria are reduced by radiation, competition for growth by the remaining organisms is also reduced. Thus, if there is temperature abuse, i.e., storage at temperatures above the refrigerator temperature that are not in accordance with 9 CFR 381.66, optimal conditions would exist for the outgrowth of spoilage organisms. If both non-refrigerator temperatures and anaerobic- or semi-anaerobic-conditions exist, the potential for outgrowth of *Clostridium botulinum* would also exist.

7. Corrective Action: The quality control system would address procedures for corrective action for failure to adhere to any of the above procedures and to dispose of product affected during the failure. Additionally, procedures would be needed to prevent reoccurrence of any failures.

If an establishment does not maintain its approved quality control system within the established standards of that program, approval of the quality control system would be subject to termination in accordance with applicable procedures (9 CFR 381.145(g)).

FSIS believes the above general requirements for the quality control system are adequate to maintain public health protections, assure accurate labeling, and provide flexibility for safe application of irradiation technology. Commenters are requested to address the adequacy of the proposed requirements and/or the need for specific provisions or detailed requirements.

Recordkeeping

A written record of the process (quality control system), monitoring activity, and corrective action is necessary. In order for the Agency to monitor radiation processing and for the irradiation facility to be assured that safe, wholesome, and properly labeled product is being produced, the written record would be maintained by the operator for a 2-year period in accordance with 9 CFR 381.177(a).

Proposed Rule

The following regulatory changes are proposed to provide poultry product irradiation procedures in Part 381 of the Federal poultry products inspection regulations:

List of Subjects in 9 CFR Part 381

Irradiation of poultry product, Labeling of irradiated poultry product, Treatment of poultry product to control foodborne pathogens.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

1. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

2. Section 381.19 would be amended by adding a new paragraph (g) to read as follows:

§ 381.19 Application for inspection; required facilities.

* * * * *

(g) *Irradiation facilities.* Applicants for inspection whose processing is limited to irradiation of packaged poultry product while in the custody of the establishment need not submit information required by this section, *provided* the applicant has submitted to the Administrator a proposed quality control system as specified in § 381.149 of this part. All applicants for inspection whose operations include irradiation and other processing would submit, to the Administrator, a proposed quality control system as specified in section 381.149 of this part, in addition to information required in this section.

3. The "Reserved" designation of § 381.135 would be removed and the following text would be added:

§ 381.135 Irradiated poultry product.

(a) The labeling of packages of poultry product irradiated in conformance with § 381.147(f)(4) of this part must bear the following logo along with a statement such as, "Treated with radiation" or "Treated by irradiation," in addition to all other labeling requirements of this subpart. The logo must be placed prominently and conspicuously in conjunction with the required statement and be colored green. The statement must appear as a qualifier contiguous to the product name and in letters of the same style, color, and type as the product name. Letters used for the qualifying statement shall be no less than one-third the size of the largest letter in the product name. Any labeling bearing the logo and any wording of explanation with respect to this logo must be approved as required by subparts M and N.

(b) The product label must bear the handling statement "Keep Refrigerated" or "Keep Frozen," as appropriate, in conformance with § 381.125 of this subpart.

(c) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the above stated requirements. Such statements must not be false or misleading.

4. Section 381.147(f)(4) would be amended by adding a new class of substance "Radiation Sources," in alphabetical order, to read as follows:

§ 381.147 Restrictions on the use of substances in poultry products.

* * * * *

(f) * * *

(4) * * *

Class of substances	Substance	Purpose	Products	Amount
Radiation sources.....	Ionizing radiation sources as approved in 21 CFR 179.26(a).	For control of food-borne pathogens.	Fresh or frozen, uncooked, packaged poultry products that are: (1) Whole carcasses that are "ready-to-cook," which includes such poultry products as fresh or frozen, uncooked ground, hand-boned, and skinless poultry, (2) mechanically separated poultry—a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses.	Minimum absorbed does of 1.5 kiloGray (150 kilorads) to a maximum absorbed does of 3.0 kiloGray (300 kilorads).

* * * * *

5. The heading of paragraph (e) of § 381.145 would be revised and paragraphs (e)(1) and (e)(3) would be revised to read as follows:

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

* * * * *

(e) *Evaluation and Approval of Quality Control Programs or Systems.*

(1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) or (d) of this section or § 381.149 of this subpart. If it is determined by the Administrator, on the basis of the evaluation, that the total quality control system, partial quality program, or quality control system for irradiation facilities will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulation thereunder, the total quality control system, partial quality control program, or quality control system for irradiation facilities will be approved and plans will be made for implementation under departmental supervision.

* * * * *

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system, partial

quality control program, or quality control system for irradiation facilities to assure compliance with the requirements of the Act and regulations thereunder. With the exception of a quality control system for irradiation facilities, as specified in § 381.149 of this subpart, the Secretary shall continue to provide the Federal inspection necessary to carry out the responsibilities of the Act.

* * * * *

6. The heading of paragraph (g) of § 381.145 would be revised, paragraph (g)(2) would be revised, and a new paragraph (g)(4) would be added to read as follows:

* * * * *

(g) Termination of Quality Control Programs or Systems.

* * * * *

The approval of a total plant quality control system, partial quality control program, or a quality control system for irradiation facilities may be terminated upon the establishments's receipt of a written notice from the Administrator under the following conditions:

* * * * *

(4) If approval of a quality control system for irradiation facilities, as specified in § 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

* * * * *

7. The "Reserved" designation of § 381.149 would be removed and the following text would be added:

§ 381.149 Irradiation of poultry product to control foodborne pathogens.

(a) Definitions of food irradiation terms:

(1) *Absorbed dose* is the amount of energy imparted by ionizing radiation to a quantity of product.

(2) *Bulk density* is the mass (weight) of a product unit divided by its total volume.

(3) *Dose mapping* is the identification of the regions of minimum and maximum absorbed dose in a product unit.

(4) A *dosimeter* is the device for measuring absorbed dose.

(5) *Dosimetry* is the process of measuring absorbed dose.

(6) *Ionizing radiation* is radiation with sufficient energy to cause the removal of electrons from atoms or molecules, thereby creating ions.

(7) *Irradiate* means to expose a material to ionizing radiation.

(8) A *product unit* is the volume of product, made up of one or more packages of product, which is collectively transported past the radiation source (e.g., in boxes or totes or on pallets or carriers).

(9) A *production lot* is the quantity of like product units designated as such by the operator of the irradiation facility or their agent to be processed in no more than one continuous shift of up to 8 hours.

(10) *Radiation source* is the radioactive material (i.e., cobalt-60) or machine that emits ionizing radiation.

(11) *Source activity decay* is the decrease in the radioactivity of radionuclide source material (i.e. cobalt-60) with the passing of time.

(12) *Traceability* is the capacity, through documentation, to relate an end-point measurement to recognized standards.

(b) Poultry product may be treated to reduce foodborne pathogens by the use of ionizing radiation as identified in § 381.147(f)(4) of this Subpart. Only irradiation facilities operating under a FSIS-approved quality control system, in accordance with paragraph (c) of this section, may irradiate poultry product for food uses.

(c) A description of the quality control system must be sent to the Administrator identifying the responsible official for quality control and stating that all data and information generated by the system will be maintained to enable the Department to monitor compliance. The quality control system will be evaluated and approved in accordance with § 381.145(e) of this subpart. A copy of the description will be placed on file in the irradiation facility and be available to any duly authorized representative of the Secretary. At a minimum, the operator of the irradiation facility must establish and comply with a quality control system which provided for the following:

(1) *Licensing, Sanitation, and Facility.* (i) Provide documentation showing that the irradiation facility is licensed and/or possesses radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

(ii) Provide documentation showing that the irradiation facility is registered with the Occupational Safety and Health Administration (OSHA) or the appropriate State government acting under authority granted by OSHA.

(iii) Procedures to ensure that the irradiation facility complies with the applicable provisions of subpart H of this part, as determined by the Administrator.

(iv) Procedures to ensure that, if the facility has no refrigerated storage capacity, adequate numbers of refrigerated units (such as trucks or carriers) will be made available during the radiation processing of poultry.

(2) *Training.* (i) Provide a statement by the operator certifying that the irradiation facility personnel would operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(ii) Provide a statement by the operator certifying that the facility personnel have been trained in quality control, food technology, irradiation processing, and radiation health and safety.

(3) *Poultry Product; Packaging, handling.* (i) Procedures to ensure that each production lot of packaged poultry is accompanied by a certificate which states that the food-contact packaging material is guaranteed by the supplier as complying with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and regulations in 21 CFR 179.45 for food irradiation processing and that the food-contact packaging material is air-permeable, but does exclude moisture and microorganisms from penetrating the package barrier.

(ii) Procedures to ensure that product units throughout each production lot are uniform in size, weight, thickness, and orientation to the radiation source.

(iii) Procedures to ensure that packages are distributed throughout each production lot uniformly with respect to package stacking arrangements bulk density, and orientation of the packages to the radiation source.

(iv) Procedures to ensure that there is only one product type.

(v) Procedures to ensure that product temperature is kept uniform within a production lot, such that fresh refrigerated product is processed separately from frozen product.

(vi) Procedures to ensure that product unit bulk density is uniform throughout a production lot.

(vii) Procedures to ensure that product is kept intact and in sealed packages.

(viii) Procedures to ensure that product is not reirradiated.

(ix) Procedures to ensure that non-irradiated product is not commingled with irradiated product.

(x) Procedures to ensure that irradiated product within each production lot is identified to permit product recall.

(xi) Procedures to dispose of poultry with damaged packaging or poultry which has been improperly irradiated.

(4) *Dosimetry.* (i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (e.g., time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 6 months.

(iv) Procedures for assuring the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(vi) Procedures for verifying routine dosimetry (i.e., assuring each production lot receives the total absorbed dose). Each production lot must have at least one dosimeter positioned at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.

(5) *Labeling.* Procedures for verifying that the product is accurately and appropriately labeled in accordance with § 381.135.

(6) *Transportation, Storage, and Handling.* Procedures for assuring that temperature and time requirements of subpart I, § 381.66 are maintained during shipping of the poultry product to the irradiation facility, radiation processing, storage, and shipping of poultry product to the point of purchase.

(7) *Corrective Action.* (i) Procedures for corrective action for failure to adhere to any of the above procedures.

(ii) Procedures to dispose of product affected during the failure to adhere to any of the above procedures.

(iii) Procedures to prevent reoccurrence of any failures to adhere to any of the above procedures.

(d) The quality control system shall be subject to periodic review, and the approval of such system may be terminated in accordance with § 381.145(g) of this subpart.

(8.) Section 381.175 would be amended by adding a new paragraph (b)(4) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(4) Records of irradiation as required by § 381.149 fo this part.

Done at Washington, DC, on: April 17, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 92–10340 Filed 5–5–92; 8:45 am]

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